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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,526	11/03/2000	Gerald Horn	HORN003	6897

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EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/26/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/705,526

Applicant(s)
Horn

Examiner
Zohreh Fay

Art Unit
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

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Claims 1-21 are presented for examination.

Claims 1-6 and 19 are rejected under 35 U.S.C. 112 first paragraph, because the specification while being enabling for certain compounds, does not reasonably provide enablement for the broad phrase of “ a compound characterized by its ability to disrupt endogenous compounds which stimulate dilator muscles of the eye”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFE1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (Bdaps 1986) at 547 the court recited eight factors:

- 1) The quantity of experimentation necessary,
- 2) The amount of direction or guidance provided
- 3) The presence or absence of working examples
- 4) The nature of the invention
- 5) The state of the art
- 6) The relative skill of those in the art
- 7) The predictability of the art
- 8) The breadth of the claims.

Applicant fails to set forth the criteria that define “ a compound characterized by its ability to disrupt endogenous compounds which stimulates dilator muscles of the eye”.

Additionally, applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. The pharmaceutical art is unpredictable requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all “compound characterized by its ability to disrupt endogenous compounds which stimulate dilator muscles of the eye”, necessitating an exhaustive search for the embodiment suitable to

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practice the claimed invention. Applicant fails to provide information sufficient to practice the claimed invention, absence undue experimentation.

Claims 13-15 are rejected under 35 U.S.C. 112 second paragraphs as being indefinite. Claims 13-15 is indefinite failing to set forth the condition, which the treatment is *Such claims fail to set forth* being used for the purpose for administration of an alpha 1 antagonist.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5-17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by galin (U.S. patent 4,443,441).

Galin teaches an alpha 1 ^eadren~~ner~~gic antagonist, phentolamine in a pharmaceutical formulation as a minotic agent used for pupil dilation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dougherty U.S. patent 4,515,295. Dougherty teaches the use of an eye drop dispenser for administering eye drops. See Column 1, lines 12-20. The above reference differs from the claimed invention in the presence of an agent, which stimulates the dilation of the muscle of the eye and also the size of the inner surface of the barrel. It would have been obvious to a person skilled in the eye to use

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any eye medication in an eyedropper in ophthalmic field. The determination of the inner surface of a barrel is considered to be within the skill of the art in the absence of evidence to the contrary. One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to an eye dropper with a hollow barrel comprising two ends and a means for dispensing the medication. To add a specific component to an eye dropper does not create a patentably distinct eye dropper. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 20-21 are properly rejected under 35 U.S.C. 103.

Fay/dl.

ZOHREN FAY
PRIMARY EXAMINER
GROUP 1200

